



May 20, 2021

Possis Medical, Inc.  
Mike Burnside  
Sr Regulatory Affairs Associate  
9055 Evergreen Blvd., N.w.  
Minneapolis, Minnesota 55433-8003

Re: K080806

Trade/Device Name: Angiojet Ultra Spiroflex VG Thrombectomy Set  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy catheter  
Regulatory Class: Class II  
Product Code: QEZ

Dear Mike Burnside:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 4, 2008. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, [Gregory.Oconnell@FDA.HHS.gov](mailto:Gregory.Oconnell@FDA.HHS.gov).

Sincerely,

**Gregory W.  
O'Connell -S**

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Gregory W. O'Connell -  
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Date: 2021.05.20  
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Gregory O'Connell  
Assistant Director  
DHT2C: Division of Coronary  
and Peripheral Intervention Devices  
OHT2: Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR - 4 2008

Possis Medical, Inc.  
c/o Mr. Mike Burnside  
Sr. Regulatory Affairs Associate  
9055 Evergreen Boulevard NW  
Minneapolis, MN 55433-8003

Re: K080806  
AngioJet Ultra Spiroflex VG Thrombectomy Set  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy Catheter  
Regulatory Class: Class II (two)  
Product Code: DXE  
Dated: March 20, 2008  
Received: March 21, 2008

Dear Mr. Burnside:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Bram D. Zuckerman*

 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



**Section 5 – 510(k) Summary**

**Submitter:** Possis Medical, Inc.  
9055 Evergreen Boulevard NW  
Minneapolis, MN 55433-8003 USA

**Contact Person:** Mike Burnside  
Sr. Regulatory Affairs Associate  
Phone: (763) 780-4555  
Fax: (763) 780-2227  
Email: [mike.burnside@possis.com](mailto:mike.burnside@possis.com)

**Date Prepared:** March 20, 2008

**Trade Name:** AngioJet® Ultra Spiroflex® VG Thrombectomy Set

**Classification:** 870.5150

**Product Code:** DXE

**Predicate Device(s):** The subject devices are equivalent to the following devices:

- K960970 AngioJet Rapid Thrombectomy System – Pump Set
- K972610 AngioJet LF140 Catheter
- K042874 AngioJet XMI-RX Thrombectomy Catheter
- K071342 AngioJet XPEEDIOR® Thrombectomy Set (reference device-design only)
- K072269 AngioJet DVX® Thrombectomy Set (reference device-design only)
- K072769 AngioJet XMI®, XVG®, & Spiroflex® Thrombectomy Sets (reference device-design only)
- K073441 AngioJet AVX® Thrombectomy Set (reference device-design only)

**Device Description:** Each AngioJet Ultra Thrombectomy Set is a sterile, single use, disposable set that includes the Thrombectomy Catheter and Pump in one combined unit. The AngioJet Ultra Thrombectomy Set is used with the AngioJet Ultra Console.

**Intended Use:** The AngioJet Ultra Spiroflex VG Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from infra-inguinal peripheral arteries  $\geq 3$  mm in diameter.

**Functional and Safety Testing:** Representative samples of the devices underwent bench testing, including but not limited to mechanical testing, biocompatibility, sterility, comparative testing to demonstrate appropriate functional and performance characteristics.

**Conclusion:** Possis Medical, Inc. considers the AngioJet Ultra Spiroflex VG Thrombectomy Set to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.